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**Notice of Allowability**

Application No.

10/690,077

Examiner

Sumesh Kaushal Ph.D.

Applicant(s)

MACLAUGHLIN ET AL.

Art Unit

1633

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 12/15/05.
2. ☒ The allowed claim(s) is/are 24,26-28,32,33 and 35.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☐ All    b) ☐ Some\*    c) ☐ None    of the:
    1. ☐ Certified copies of the priority documents have been received.
    2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).
  - \* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
  - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
    - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
  - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

1. ☒ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date \_\_\_\_\_
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☐ Interview Summary (PTO-413), Paper No./Mail Date \_\_\_\_\_
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other \_\_\_\_\_

### EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Marina Heusch on 02/28/06.

The application has been amended as follows:

#### IN THE CLAIMS

**Claim 34** is canceled

**Claim 24.** (Currently Amended) A cell-matrix structure for implantation into a patient comprising a polymeric matrix and cells attached thereto in an amount sufficient to stop or regress abnormal cell or tissue growth in the patient, wherein the cells in the cell-matrix structure are genetically engineered to stably express Mullerian Inhibiting Substance (MIS).

### **IN THE ABSTRACT**

The abstract is replaced with following text.

-- Normal cells, such as fibroblasts or other tissue or organ cell types, are genetically engineered to express biologically active, therapeutic agents, such as proteins that are normally produced in small amounts, for example, MIS, or other members of the TGF-beta family Herceptin<sup>TM</sup>, interferons, and anti-angiogenic factors. These cells are seeded into a matrix for implantation into the patient to be treated. Cells may also be engineered to include a lethal gene, so that implanted cells can be destroyed once treatment is completed. Cells can be implanted in a variety of different matrices. In a preferred embodiment, these matrices are implantable and biodegradable over a period of time equal to or less than the expected period of treatment, when cells engraft to form a functional tissue producing the desired biologically active agent. Implantation may be ectopic or in some cases orthotopic. Representative cell types include tissue specific cells, progenitor cells, and stem cells. Matrices can be formed of synthetic or natural materials, by chemical coupling at the time of implantation, using standard techniques for formation of fibrous matrices from polymeric fibers, and using micromachining or microfabrication techniques. These devices and strategies are used as delivery systems via standard or minimally invasive implantation techniques for any number of parenterally deliverable recombinant proteins, particularly those that are difficult to produce in large amounts and/or active forms using conventional methods of purification, for the treatment of a variety of conditions. --

## REASONS FOR ALLOWANCE

The following is an examiner's statement of reasons for allowance:

Claims 24, 26-28, 32-33 and 35 are free of prior art of record. The prior art does not teach or suggest a cell-matrix structure for implantation into a patient comprising a polymeric matrix and cells attached thereto in an amount sufficient to stop or regress abnormal cell or tissue growth in a patient, wherein the cell in the cell-matrix structure are genetically engineered to stably express Mullerian Inhibiting Substance (MIS).

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

- *US Pat No.6,692,738 B2, 2004,*
- *Stephen et al, Tissue-engineered cells producing complex recombinant proteins inhibit ovarian cancer in vivo. Proc Natl Acad Sci 98(6):3214-9, 2001 (ref of record PTO 1449).*
- *Stephen et al Highly purified mullerian inhibiting substance inhibits human ovarian cancer in vivo. Clin Cancer Res. 8(8):2640-6. 2002 (ref. of record PTO1449)*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sumesh Kaushal Ph.D. whose telephone number is 571-272-0769. The examiner can normally be reached on Mon-Fri. from 9AM-5PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dave Nguyen can be reached on 571-272-0731.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to **571-272-0547**. For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199. The fax phone number for the organization where this application or proceeding is assigned is **571-273-8300**

  
SUMESH KAUSHAL, PH.D.  
PRIMARY EXAMINER